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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,807	08/21/2003	Craig A. Rosen	PS735	7993

22195 7590 11/18/2005

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EXAMINER	
XIE, XIAOZHEN	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,807	ROSEN ET AL.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) *37,38 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-36 and 39-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20051017*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Applicant's amendment of the claims, the Title and the Inventorship filed 17 October 2005 is acknowledged.

In view of the papers filed 17 October 2005, the inventorship in this nonprovisional application has been changed by the deletion of following names from the list of inventors: George A. Komatsoulis, Charlses E. Birse, Gil H. Choi, Jian Ni and Adam Bell.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

The Information Disclosure Statement (IDS) filed 17 October 2005 has been entered.

Election/Restriction

Applicant's election of Group III (i.e., drawn to the isolated antibodies of claim 13), and election of a single polypeptide sequence, SEQ ID NO: 213 (HQAHD50), in the reply filed on 17 October 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claims 25-47 correspond to the elected invention. Newly submitted claim 48 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 48 is drown to a method of detecting a plypeptide using the antibody.

Inventions III and Newly submitted claims 25-47 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Invention III can be used for therapeutic purpose.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 48 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Sequence Compliance

The application is now in compliance with the sequence rules, 37 CFR 1.821-1,825, in view of Applicant's amendment received on 17 October 2005.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

The instant claims are drawn to an isolated antibody that specifically binds to a polypeptide of: a) SEQ ID NO: 213; b) at least 30 contiguous amino acid residues of SEQ ID NO: 213; and c) at least 50 contiguous amino acid residues of SEQ ID NO: 213. Claims are also presented to cells and hybridomas that produce such antibodies. The specification discloses a polypeptide of SEQ ID No: 213 as a secreted protein encoded by HQAHD50. The specification discloses that the antibody that specifically binds to the polypeptide may act as an agonist or antagonist of the polypeptide of the instant invention, and may be used to purify, detect, and target the polypeptide in both *in vitro* and *in vivo* diagnostic and therapeutic methods (specification, pp. 350, lines 18 to pp. 352, line 6). The utility of the claimed antibody resides in the polypeptide it binds. The specification, however, fails to provide objective evidence of any function for the protein.

Further, the specification does not disclose any activities, diseases or conditions known to be associated with the protein. The specification asserts a number of general uses for the polypeptide on pages 407-409, including assaying protein levels in a biological sample, imaging the protein *in vivo*, generating antibody, using as a molecular weight marker, treating, preventing and/or diagnosing diseases. Without knowing the biological role of this protein or its significance, merely listing a number of possibilities as in the instant specification is not sufficient to identify or confirm a "real world" context of use. The utilities identified by the applicant are not specific or substantial. Assaying and detecting a protein of unknown function, is clearly to use it as the object of further research. Production of antibodies are useful only in research to determine the function of the protein itself: there is no "specific benefit in currently available form" to be derived from such studies. As for molecular weight marker, it could be asserted for any naturally occurring protein and does not require any feature or activity that is specific to the disclosed protein. Applicant lists a number of diseases, including cancer and immune system disorders, particularly immune cell proliferative disorders, autoimmune disorders, and immunodeficiencies caused by genetic factors, microbial pathogens, chemotherapy and radiation (specification, pp. 38, lines 1-10 and pp. 161, Table 1C), that may be diagnosed or treated by the instant invention. However, the specification has provided no evidence that changes in levels or forms of the protein correlates with a diagnosis of a specific disease, and how to use the claimed invention for the treatment or diagnosis of the disease. Clearly it requires further research.

The claimed invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. Neither the specification, nor the sequence search (see sequence search results) has indicated significant homology to any known functional protein domains. There is therefore no specific, substantial, or credible utility that is well known, apparent, or implied by the relationship of the instant polypeptide to the prior art.

The instant application has provided a description of a polypeptide, which has an as yet undetermined function or biological significance. Until some actual and specific significance as a diagnostic and/or therapeutic agent to treat cancer and immune system disorders, can be attributed to the protein and the antibody that specifically binds to it, the instant invention is incomplete, and, therefore, does not meet the requirements of 35 USC § 101 as being useful. See *Brenner v. Manson,* 383 U.S. 519, 535-36, 148 USPQ 689, 696 (Sup. Ct., 1966), noting that "a patent is not a hunting license, it is not a reward for the search, but compensation for its successful conclusion". A patent is therefore not a license to experiment. See also the revised Interim Utility Guidelines available at www.uspto.gov.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-36 and 39-45 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Xiaozhen Xie, Ph.D
October 31, 2005